

acteristics were comparable between the two cohorts (all p-values > 0.05). During median follow-up of 2.95 years, the cumulative incidence of death was 304 (17.72%) among 1716 PADT patients and 94 (5.48%) among 1716 RP patients; 66 (3.85%) and 2 (0.12%) for prostate cancer specific deaths, respectively. The PADT group had nearly 4 times higher overall mortality risk compared to those using RP (odds ratio (OR) = 3.534, 95% confidence interval (CI) = 2.801-4.464,  $p < 0.001$ ). Furthermore, patients who received PADT had significantly higher prostate cancer specific mortality compared to those using RP (OR = 30.875, 95% CI = 7.535-126.506,  $p < 0.001$ ). **CONCLUSIONS:** Overall mortality and prostate cancer specific mortality following PADT were significantly higher compared to those following RP among localized prostate cancer patients. These data do not support the use of PADT in men with clinically localized prostate cancer.

#### PCN9

##### FROM INDIRECT EVIDENCE TO DIRECT EVIDENCE: A REAL-WORLD EXAMPLE FOR THE VALUE OF INDIRECT TREATMENT COMPARISONS IN SECOND-LINE NSCLC THERAPY

Schwander B<sup>1</sup>, Chouaid C<sup>2</sup>, Vergnenegre A<sup>3</sup>, Bischoff HC<sup>4</sup>, Nuijten M<sup>5</sup>, Siebert U<sup>6</sup>, Walzer S<sup>7</sup>

<sup>1</sup>AiM GmbH - Assessment in Medicine, Research and Consulting, Loerrach, Germany, <sup>2</sup>Hôpital Saint Antoine, Paris Cedex France, <sup>3</sup>Hôpital du Cluzeau Centre Hospitalier Universitaire (CHU) de Limoges, Limoges, France, <sup>4</sup>Thoraxklinik Heidelberg GmbH, Heidelberg, Germany, <sup>5</sup>Ars Accessus Medica, Amsterdam (Jisp), The Netherlands, <sup>6</sup>UMIT - University for Health Sciences, Medical Informatics and Technology / ONCOTYROL - Center for Personalized Cancer Medicine, Hall i.T. / Innsbruck, Tyrol, Austria, <sup>7</sup>F. Hoffmann-La Roche Pharmaceuticals AG, Basel, Switzerland

**OBJECTIVES:** Often new treatment options lack comparisons to treatment options which already exist on the market and which were launched several years ago. Due to such a lack of head-to-head evidence indirect treatment comparisons (ITC) are increasingly being performed. Although ITC methods are widely accepted, the results are often interpreted with caution, probably because of their lack of external validity proven by real clinical studies. **METHODS:** The first available pivotal phase-III trials for docetaxel and erlotinib in second-line non-small cell lung cancer (NSCLC) included best supportive care (BSC) as a comparator which allowed an ITC of erlotinib versus docetaxel to be performed, applying the Bucher methodology. The pemetrexed pivotal phase-III trial provided direct evidence vs docetaxel, which subsequently allowed an ITC of erlotinib vs pemetrexed to be performed. Later another phase-III trial was published comparing erlotinib vs pemetrexed, which allowed the ITC of erlotinib vs docetaxel to be re-performed. This trial and a further recently published phase-III trial directly comparing erlotinib vs docetaxel or pemetrexed, allowed the external validation of the ITC outcomes. The overall survival (OS) hazard ratios (HR) were used to produce ITC-OS HRs with 95% confidence intervals (95%CI). **RESULTS:** Comparing erlotinib versus docetaxel resulted in an ITC-OS HR of 1.25 (95%CI: 0.76-2.06,  $p = 0.381$ ). Using these ITC results to compare erlotinib to pemetrexed resulted in an ITC-OS HR of 1.26 (95%CI: 0.74-2.15,  $p = 0.392$ ). Re-performing the ITC of erlotinib versus docetaxel resulted in an ITC-OS HR of 0.95 (95%CI: 0.71-1.28,  $p = 0.736$ ). The head-to-head evidence validated those findings with an OS HR of 0.96 (95%CI: 0.77-1.21,  $p = 0.916$ ) and 0.96 (95%CI: 0.78-1.19,  $p = 0.730$ ), comparing erlotinib vs pemetrexed and erlotinib versus pemetrexed or docetaxel, respectively. **CONCLUSIONS:** Recently published clinical head-to-head evidence has confirmed the appropriateness and validity of ITC findings in second-line NSCLC.

#### PCN10

##### TARGETED THERAPY (TT) FOR FIRST LINE TREATMENT OF ADVANCED RENAL CELL CARCINOMA (RCC): AN INDIRECT COMPARISON META-ANALYSIS (ICMA)

Matheus W<sup>1</sup>, Duran MA<sup>1</sup>, Clark OAC<sup>2</sup>, Kumar A<sup>3</sup>, Ferreira U<sup>1</sup>, Botrel TEA<sup>2</sup>

<sup>1</sup>State University of Campinas, Campinas, SP, Brazil, <sup>2</sup>Evidencias, Campinas, SP, Brazil,

<sup>3</sup>University of South Florida, Tampa, FL, USA

**OBJECTIVES:** In the past, interferon (IFN) has proven to be effective in extending the survival of patients with RCC. New TT, drugs such as Sunitinib (SU), Sorafenib (SO) and Bevacizumab (BE) have been tested against IFN. Recently, a new study was published, comparing a new TT, Pazopanib (PZ) versus placebo (PLA) but not interferon. An important question arose about the relative efficacy of PZ versus other TT and IFN, given that the control group used was not an active one in the PZ trial. When head-to-head studies are lacking, an ICMA can help solving the problem of relative efficacy. Our aim was to perform an ICMA comparing TT. **METHODS:** We performed a systematic review, searching for randomized controlled trials that compared TT against IFN or PLA, or those that compared PLA versus IFN. We conducted an indirect comparison meta-analysis that used PLA as a bridge to compare the different TT. The end point of interest was progression free survival (PFS). The results are expressed as Hazard Ratio (HR), with the corresponding confidence interval of 95% (CI). **RESULTS:** We found 8 randomized controlled trials that fit our inclusion criteria. The results of the ICMA for PFS were: PZ versus SU [HR = 1.19; CI = 0.37 to 3.85]; PZ versus IFN [HR = 0.59; CI = 0.23 to 1.55]; PZ versus SO [HR = 0.75; CI = 0.22 to 2.54]; PZ X BE [HR = 0.83; CI = 0.31 to 2.24] **CONCLUSIONS:** The results showed that PZ was superior to placebo but not to IFN. The confidence intervals obtained from the analysis were very wide precluding a definitive conclusion regarding the relative efficacy of TT, although there was a trend to confirm the superiority of SU.

#### PCN11

##### SYSTEMIC THERAPY FOR COLORECTAL CANCER: PATTERNS OF CHEMOTHERAPY AND BIOLOGIC THERAPY USE IN NATIONALLY REPRESENTATIVE CLAIMS DATABASE IN THE UNITED STATES

Valluri S<sup>1</sup>, Seal B<sup>1</sup>, Ramsey S<sup>2</sup>, Sullivan SD<sup>3</sup>, Shermock K<sup>4</sup>, Sarma S<sup>5</sup>, Kreilick C<sup>6</sup>, Foltz-Boklage S<sup>6</sup>

<sup>1</sup>Bayer HealthCare Pharmaceuticals, Inc., Pine Brook, NJ, USA, <sup>2</sup>Fred Hutchinson Cancer Research Center, University of Washington, Seattle, WA, USA, <sup>3</sup>University of Washington, Seattle, WA,

USA, <sup>4</sup>Analysis by Design LLC, Columbia, MD, USA, <sup>5</sup>Independent Consultant, Wilmington, NC, USA, <sup>6</sup>Bayer HealthCare, Wayne, NJ, USA

**OBJECTIVES:** Study examined the pattern of chemotherapy and biologic therapy use by line of treatment in newly diagnosed patients with colorectal cancer (CRC). **METHODS:** Patients newly diagnosed with CRC between January 1, 2005 and June 31, 2009 and treated with systemic therapy were identified in a US-based administrative medical claims (i3 Innovus) database. Six months of patient history with no prior ICD-9 diagnosis of CRC and 1-year post-index continuous enrollment was required. Patients were followed from initial CRC diagnosis to death, disenrollment, or June 31, 2010. Chemotherapy and biologic treatments over time were analyzed to identify lines of therapy and assessed and stratified by line of therapy (1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> +), subgroup analysis was performed in metastatic CRC. **RESULTS:** Of 9876 patients, 45% received only 1<sup>st</sup> line treatment, 35% received 1<sup>st</sup> and 2<sup>nd</sup> line treatment and 20% received 3<sup>rd</sup> line and beyond. 60% of the study patients were identified as having metastasis either during the follow up period or at index date. The 1<sup>st</sup> line, 43% received an oxaliplatin-based regimen, 5% received an irinotecan-based regimen, and 46% received 5-FU alone. 2<sup>nd</sup> and 3<sup>rd</sup> line settings percentages of patients treated with irinotecan-based regimens increased from 18% to 43%, respectively, use of oxaliplatin-based regimens dropped from 42% to 22%, respectively. The proportion of subjects who used bevacizumab doubled from 1<sup>st</sup> to 3<sup>rd</sup> line regimen. Overall, use of cetuximab and panitumumab increased from 2% in the 1<sup>st</sup> line to 7%, and 23%, respectively in the 2<sup>nd</sup> and 3<sup>rd</sup> + lines of treatment. **CONCLUSIONS:** Despite treatment guidelines, a large proportion of patients received 5-FU monotherapy and capecitabine as 1<sup>st</sup> line treatment even for metastases. The use of biologics in the first line was present with use in later lines. The use of EGFR inhibitors increased in the later lines of treatment after FOLFOX and FOLFIRI with or without bevacizumab.

#### PCN12

##### SURVIVAL PATTERNS BY LINE OF TREATMENT OF STAGE IV COLORECTAL (CRC) PATIENTS FROM LOCAL ONCOLOGY PRACTICE IN THE UNITED STATES

Seal B<sup>1</sup>, Sullivan SD<sup>2</sup>, Ramsey S<sup>3</sup>, Kreilick C<sup>4</sup>, Foltz-Boklage S<sup>4</sup>, Haslip S<sup>5</sup>, Gilmore J<sup>5</sup>, Sarma S<sup>6</sup>, Asche C<sup>7</sup>, Valluri S<sup>1</sup>

<sup>1</sup>Bayer HealthCare Pharmaceuticals, Inc., Pine Brook, NJ, USA, <sup>2</sup>University of Washington, Seattle, WA, USA, <sup>3</sup>Fred Hutchinson Cancer Research Center, University of Washington, Seattle, WA, USA, <sup>4</sup>Bayer HealthCare, Wayne, NJ, USA, <sup>5</sup>Georgia Cancer Specialists, Atlanta, GA, US, Atlanta, GA, USA, <sup>6</sup>Independent Consultant, Wilmington, NC, USA, <sup>7</sup>University of Illinois, Peoria, IL, USA

**OBJECTIVES:** Stage IV CRC patients have varying survival results from multiple lines of treatment. The objective of this study was to evaluate in a real world context, the impact of adding a third line of chemotherapy to a stage IV CRC population. **METHODS:** The Georgia Cancer Specialist database (2005-2011) was used. Patients with stage IV colon or rectal cancer and treated with chemotherapy were followed from initial CRC diagnosis until death, study end or lost to follow-up. Patients were stratified into lines and type of protocol for treatments. Kaplan-Meier curves were used to compare the overall survival results between lines of therapy. **RESULTS:** There were 335 patients with confirmed stage IV CRC of which 35% received one protocol, 27% two protocols, and 38% received three or more protocols. The most common first line agents consisted of FOLFOX with or without bevacizumab or FOLFIRI with or without bevacizumab. Some single agent 5FU or 5FU with bevacizumab was observed in first line. The most common second agents were the FOLFOX or FOLFIRI not given in first line. However single agent capecitabine, cetuximab and bevacizumab were observed. In third line similar single agents but more panitumumab and capecitabine combinations were observed. Of those treated with second line (45) and three or more lines (75). The median survival was no different between the patients that received second line and those that went on to a third line (Log-Rank  $P = 0.1249$ ). **CONCLUSIONS:** The addition of adding a third line to a stage IV population that already received a second line failed show an association to increase survival. The benefit of adding a third line may benefit some patients and the particular combination of therapy needs to be explored in future studies.

#### PCN13

##### COST-EFFECTIVENESS ANALYSIS OF Nilotinib VERSUS DASATINIB IN PATIENTS WITH IMATINIB-RESISTANT OR IMATINIB-INTOLERANT CHRONIC MYELOID LEUKEMIA (CML)

Niu X, Hay J  
University of Southern California, Los Angeles, CA, USA

**OBJECTIVES:** To compare the economic impact from US societal perspective of Nilotinib and Dasatinib as second-line therapies in treatment of CML patients with Imatinib resistance or intolerance by conducting a cost-effectiveness analysis. **METHODS:** A Markov simulation model was developed to estimate quality adjusted life years (QALYs) and expected costs using data from head-to-head comparative clinical trials. Costs in the model included medication cost, hospitalization cost, physician fee, laboratory test fee, adverse events cost, and value of waiting time and were obtained from published literature and government and organization websites. All costs were adjusted to 2011 US dollars. The treatment pattern was assumed to be 800mg/day for Nilotinib, or 100mg/day for Dasatinib in the chronic phase and 140mg/day in the advanced phase. Treatment was evaluated up to progression of the disease, best supportive care and up to death, operating 80 cycles of 3 months. Switching from one product to the other due to severe adverse events was also considered. Sensitivity analyses were performed to test the robustness of the results. **RESULTS:** In the base case analysis, the total cost for treatment with Nilotinib was \$150,966, and Dasatinib was \$126,672. Patients treated with Nilotinib gained 0.57 more life years, or 0.49 more QALYs, compared with Dasatinib. The incremental cost-effectiveness ratio (ICER) for Nilotinib therapy was \$49,467/